DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
Atlanta District
Southeast Region
60 Eighth Street, N.E.
Atlanta, Georgia 30309

Telephone: 404-253-1200
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August 3, 2004

VIA FEDERAL EXPRESS

Mr. Robert W. Maynard
President and CEO
Piedmont Hospital, Inc.
Blood Transfusion Service
1968 Peachtree Road, N.W.
Atlanta, Georgia 30309

WARNING LETTER
(04-ATL-18)

Dear Mr. Maynard:

An investigator from the Food and Drug Administration (FDA) conducted an inspection of your blood transfusion service, located at 1968 Peachtree Road, NW, Atlanta, Georgia, on April 26 – May 7, 2004. The inspection revealed numerous significant deviations from applicable current Good Manufacturing Practice (cGMP) regulations for blood and blood components, Title 21, Code of Federal Regulations (CFR), Parts 211, 606, and 640. The investigator documented these deviations on a Form FDA-483 that was presented and discussed with management at the conclusion of the inspection. The violations documented cause your blood products to be adulterated, within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The deviations included, but are not limited to, the following:

1) Your staff failed to follow procedures to expedite transfusion in life-threatening emergencies, including maintaining complete documentation justifying the emergency action [*21 CFR 606.151(e) and 21 CFR 211.100(b)*].

Specifically, from March 7 – 8, 2004, your staff released five units of blood that were transfused prior to receiving antigen and/or compatibility test results from the American Red Cross (ARC). Your staff failed to complete an emergency release form according to the Standard Operating Procedure (SOP) titled "Urgent Requirement for Blood."

2) Your facility failed to establish, maintain, and follow a procedure for reporting Biological Product Deviations (BPDs) to the Center for Biologics Evaluation and Research (CBER) [21 CFR 606.171].

Specifically, your staff failed to notify CBER in a BPD Report of the emergency release of five units of blood prior to receiving antigen and/or compatibility test results.

3) Transfusion service personnel do not have adequate training and experience to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess [21 CFR 606.20(b)].

Specifically, the FDA investigator's review of training records for four blood bank technicians found that their blood bank competency assessments had not been performed annually, according to the SOP titled "Competency Assessment." The dates of their last annual assessments were 12/01/2001, 1/20/2002, 5/22/2002 & 7/21/2002, respectively.

4) Your staff failed to follow written SOPs, that include but are not limited to, investigating recipient reactions, compatibility testing, and distribution of blood and blood components for transfusion [21 CFR 211.100(b)].

Specifically, your transfusion service failed to follow your SOP titled "Sentinel Event Reporting" in that the Director of Risk Management and the Vice President of Patient Advocacy were not informed until 4/19/04 and 4/26/04, respectively, of a possible hemolytic transfusion fatality which occurred in your hospital on 3/12/04.

5) Your staff failed to maintain records concurrently with the performance of each significant step in the compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced [21CFR 606.160], in that:

a) On March 7, 2004, a technician entered compatibility test results for two blood units ([redacted] #[redacted]) into the blood bank computer system as compatible. However, the actual test results were not obtained from ARC (who performed the compatibility testing) and there were no compatibility test records at your facility to support the results that were entered in the computer by your blood bank technician.

b) On April 27, 2004, the Blood Bank Supervisor provided our investigator with a document showing the antigen test results for blood unit #[redacted] and unit #[redacted]. Your staff failed to maintain significant blood testing steps, including:

1) There was no record of the controls utilized for the antigen testing.

2) The antigen test record failed to include the technician's initials and the date that the testing was performed.

6) **Your facility failed to maintain the following records as required by 21 CFR 606.160(b):**

a) Compatibility test records that accompany units received from ARC, which document the crossmatch results, donor number, technician identification, donor and recipient blood type & Rh.

b) Reference Laboratory Interim Reports, which document results of testing that were performed (antibody ID), type of units issued, and compatibility results.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood products issued by your transfusion facility are in compliance with the Act and the cGMP regulations. Your failure to correct these deviations may result in regulatory action being taken by FDA without further notice. Possible action may include seizure or injunction.

We acknowledge receipt of your letter dated May 27, 2004, submitted to this office in response to the Form FDA-483, addressing the observations and stating the corrective actions either taken or to be taken.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these deviations and to prevent their reoccurrence. You should also provide complete documentation to demonstrate that the promised corrective actions are being appropriately implemented, such as employee training records, written standard operating procedures, or other records demonstrating corrective action. If you cannot complete corrections within 15 working days, state the reason for the delay and the time period within which corrections will be completed.

Please send your response to James C. MacLaughlin, Compliance Officer, at the address noted in the letterhead.

Sincerely,

Mary Woleske

Mary H. Woleske
District Director
Atlanta District